IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

UNITED STATES OF AMERICA *ex rel.* DR. CINDY BUCKMASTER	)	
	)	Civil Action No. 3:22-cv-00059
	)	Jury Trial Requested
Plaintiff-Relator,	)	
v.	)	
BAYLOR COLLEGE OF MEDICINE	)	
Defendant.	)	

FIRST AMENDED COMPLAINT
FOR VIOLATIONS OF THE FALSE CLAIMS ACT

Relator brings this action on behalf of the United States against Baylor College of Medicine (BCM) to recover treble damages and civil penalties for violations of the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, and other relief for retaliation. For the First Amended Complaint (FAC), Relator alleges as follows.

INTRODUCTION

1. BCM is an institution that has received billions of dollars in federal grants from the National Institutes of Health (NIH) to be used for its biomedical research to improve public health and medical treatment of humans.

2. Animals are used in research to advance the scientific understanding and treatment of human disease and conditions such as breast and prostate cancer, heart disease, central nervous system disease, diabetes, liver and digestive diseases, neurological disorders like epilepsy, eye diseases, newborn health and development, genetic health, allergies, and asthma.

3. Because it advances the public good, biomedical research is funded by taxpayers. Public research dollars are scarce, however, and the grant process is highly competitive. Public research grants can be awarded only to the most deserving research projects. And once received, public grant funds must be spent responsibly and in compliance with the law and grant research requirements.

4. In exchange for taxpayer money, BCM must comply with laws that govern biomedical research "to ensure the integrity and accountability" of the studies funded by the Government. As part of those requirements, BCM must also execute an Assurance and compliance certifications.

5. Federal grantees like BCM are required to minimize pain and distress in research animals to avoid negative consequences to outcomes in studies. Pain or

distress may activate the HPA axis (i.e., stress axis) and cause downstream disruptions to multiple physiological systems, confounding study results that can lead to unreliable and invalid scientific conclusions. As various scientific organizations have emphasized:

- "humane and responsible care of laboratory animals is vital to **quality research**."
- "appropriate use of anesthetics, tranquilizers, analgesics, and nonpharmacologic interventions in research animals is an ethical and **scientific imperative**."
- "pain and distress are undesirable variables in most scientific research projects and, if not relieved, can result in unacceptable animal welfare and **invalid scientific outcomes**."
- "when research involves animals, **reliable scientific results** depend on superior animal care."

(emphasis added) (American Association for Laboratory Animal Science); (American College of Laboratory Animal Medicine Position Statement on Pain and Distress in Research); (Association for Assessment and Accreditation of Laboratory Animal Care)

6. As one Government official has reminded BCM, "good animal welfare is not just [ ] for the sake of the animals, it's also for the data that's

generated. You can't have sick animals, dying animals and try to get good data out of that." When research subjects are mistreated and research protocols are not followed, the Government will not get the accurate and reliable study results it paid for.

7. Furthermore, BCM is required to employ qualified and trained individuals in certain institutional roles to ensure compliance with its grant certifications to the Government. These roles include:

- an Institutional Animal Care and Use Committee (IACUC)—a BCM animal research oversight body to ensure compliance with federal laws and grant requirements
- an Institutional Official (IO)—the BCM liaison between the IACUC and the Government
- Principal Investigators (PIs) who are responsible to ensure that they and their lab staff properly conduct biomedical research in accordance with federal grant requirements
- BCM veterinarians who have authority and access to all animals used in the biomedical research

8. These various individuals and entities within BCM are required to formally approve and monitor compliance with research "protocols" that govern the precise conditions under which the biomedical research is to be conducted.

9. In addition to Government grantors like NIH, BCM answers to the Office of Laboratory Animal Welfare (OLAW), a component of NIH that oversees all Government-funded research involving the use of animals.

10. BCM is required to submit various reports to OLAW and the grantor agency (here, NIH), including reports of any "serious or continuing noncompliance" like the violations alleged in this case. This allows OLAW to monitor compliance and flex its enforcement muscle if necessary.

11. However, BCM's biomedical research program has had "serious and continuing noncompliance" problems that have threatened the validity and reliability of its biomedical research. Put more plainly, BCM's failures have tainted the biomedical research the Government has funded. Such knowing failures have included:

- allowing unauthorized, untrained, and unqualified individuals to conduct surgeries, leading to "serious and continuing" noncompliance
- failing to comply with proper surgical procedures or to properly perform surgeries, and botching surgeries
- failing to properly administer anesthesia during surgeries and pain relief medications

- violating DEA and OLAW requirements for drug use and maintenance, and administering expired drugs to research animals in violation of DEA and OLAW requirements
- failing to properly monitor the health of research animals post-operatively
- failing to follow IACUC-approved protocols
- causing illness and death to research animals, unrelated to experimental causes.

12. Because these failures are systemic, BCM also put at risk state grants awarded by funders such as Cancer Prevention and Research Institute of Texas (CPRIT) and private grants awarded by funders such as the American Heart Association, March of Dimes, McNair Medical Institute, Albert and Margaret Alkek Foundation, John S. Dunn Foundation, National Multiple Sclerosis Society, American Cancer Society, and Helis Medical Research Foundations, but those damages are not sought here.

13. BCM made numerous false certifications of compliance with federal requirements to obtain the grant funds in the first instance and to maintain its funding. In these instances, taxpayer funds and animal lives are wasted, a clear violation of the public's trust.

14. BCM was repeatedly put on notice of what the Government considered material to its decision to pay claims under these grants. OLAW warned BCM, among other things, to ensure the grants are not "charged for any unauthorized animal activities" or "unapproved drugs or procedures" and that "data acquired during the conduct of activities not approved by [BCM's IACUC] usually cannot be published."

15. Some of the labs that received the most money from the Government were the worst of the worst violators. And despite the knowledge of BCM senior executives including its IACUC officials, IO, PIs, and veterinarians, BCM knowingly failed to correct "serious and continuing" violations. Further, BCM and its officials hid noncompliance from Government officials despite repeated warnings from Government officials:

> The assurance states, signed by your institutional official, that you will report. That is the absolute expectation, and you'll report promptly and you'll fix things promptly. If investigators think, well, I better not report this because it could impact my grant, your grant will be much more impacted if the institution as a whole, doesn't fulfill this requirements [sic] under the assurance. . . . **In**

> **Washington they always say the cover up is worse than the crime**. So it's extremely important that you all continue reporting, continue monitoring your program, to protect your research funds.

(emphasis added) (OLAW Deputy Director Axel Wolff)

16. Because of BCM's cover-up, OLAW did not know of "serious and continuing" noncompliance and the Government has continued to fund BCM's biomedical research.

17. When occasionally caught, BCM falsely promised it would take corrective action and fraudulently led the Government to believe that it had followed through on promised corrective action. When OLAW was on notice of material noncompliance, OLAW imposed sanctions.

18. In 2018, OLAW placed BCM on enhanced reporting—only one step removed from the termination of federal funding—due to "ongoing serious programmatic noncompliance" caused by its failure to implement a surgical training and assessment program. To prevent the Government from turning off the funding spigot, BCM promised OLAW that it would not allow untrained individuals to perform surgeries. Despite its promises to the Government, BCM knowingly allowed dozens of untrained and unqualified individuals to perform hundreds of surgeries indicative of "serious and continuing" noncompliance.

19. BCM's violations compromised the validity and reliability of the data from the experiments, calling into serious question the results of research emanating from untrained individuals performing surgeries, unhealthy and distressed animals, and botched surgeries.

20. In her role as Director of the Center for Comparative Medicine (CCM), Relator persisted in trying to fix "serious and continuing noncompliance" in BCM's biomedical research program. Dr. Buckmaster's efforts were met with strong resistance by BCM leadership until Relator was terminated for her whistleblowing activities. But for filing this lawsuit, BCM's conduct will continue unabated.

21. Through its fraudulent course of conduct, BCM knowingly submitted or caused the submission of false or fraudulent claims to the Government, in violation of the False Claims Act, and the Government paid those claims.

22. The amount of Government funding at issue in this fraudulent scheme is significant. Federally funded research is big business for BCM. Since 2016, BCM received over $2 billion from NIH. Over $325 million was for Government claims paid to BCM labs in which there has been "serious or continuing noncompliance."

23. The False Claims Act is the appropriate tool to remedy this fraudulent scheme according to the Deputy Assistant Attorney General for the United States

Department of Justice: "Undoubtedly, the Department will continue to rely heavily on whistleblowers to help root out the misuse and abuse of taxpayer funds." https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act

24. For example, in 2019, the Department of Justice recovered over $100 million from Duke University for False Claims Act violations relating to biomedical research failures caused by only one research technician. The case was litigated by the whistleblower and the settlement approved by DOJ: "Today's settlement demonstrates that the Department of Justice will pursue grantees that knowingly falsify research and undermine the integrity of federal funding decisions….This settlement sends a strong message that fraud and dishonesty will not be tolerated in the research funding process…. We will continue to take appropriate legal measures to ensure a fiscally sound system that protects grant funds." https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related

THE PARTIES

25. Relator alleges based upon personal knowledge, relevant documents, and on information and belief, the facts set forth in this FAC. Relator has extensive first-hand knowledge of BCM's pattern and practice alleged in this FAC as a senior executive of BCM from July 2005 to October 2, 2019. Relator was

terminated on that date because of lawful acts by Relator to stop one or more violations of the False Claim Act and lawful acts by Relator in furtherance of an action under 31 U.S.C. § 3730.

26. Relator has standing to bring this action under 31 U.S.C. § 3730(b)(1). Relator's allegations have not been publicly disclosed as that term is defined under 31 U.S.C. § 3730(e)(4)(A). Even if Relator's allegations had been publicly disclosed, Relator is the original source of the allegations in this FAC under 31 U.S.C. § 3730(e)(4)(b).

27. Relator has complied with all procedural requirements of the laws under which this FAC is brought.

The United States

28. The United States is the "real party in interest" in a declined False Claims Act qui tam case. *See, e.g., United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009).

Relator

29. Relator is Cindy Buckmaster, Ph.D. (Dr. Buckmaster), who brings this False Claims Act qui tam case on behalf of the United States.

30. Relator is highly respected and widely known in the lab animal care scientific research community. Relator is past-Chair of Americans for Medical Progress (and was the then-Chair during the retaliation period), the President of the

Texas Society for Biomedical Research, past-President of the Laboratory Animal Welfare Training Exchange, and past-President of the American Association for Laboratory Animal Science, among numerous other scientific affiliations.

31. Relator has authored scientific articles, speaks to audiences around the globe, and contributes to publications relating to the use of animals in biomedical research. Relator is also frequently interviewed by the media based on her knowledge of basic research and laboratory animal care. This was also true during the retaliation period. Relator holds half a dozen certifications in animal welfare and has received 8 different awards such as "Above and Beyond Award for dedication above and beyond the call of duty" from the National Animal Interest Alliance (NAIA), a fraction of the experience and accolades Relator has received over her decades-long career in animal research.

32. Relator was hired by BCM's Center for Comparative Medicine (BCM-CCM) in July 2005 as the Associate Director of Training, initially to develop, implement, and monitor a Training and Quality Assurance program that incorporated multiple levels of inspection and peer review. Relator was promoted to the position of BCM-CCM's Associate Director of Training and Operations in July 2006 and then its Director in July 2011. Relator remained the Director until her termination on October 2, 2019.

33. As Director, Relator oversaw the entire animal care program for the animals involved in biomedical research at BCM. Relator successfully developed a comprehensive training and education program for laboratory animal technicians of all levels, including for 200+ staff members supporting a diverse range of laboratory animals across multiple buildings. In addition to CCM technician training, Relator also implemented environmental enrichment, safety, and species-specific trainings to name a few of her other accomplishments. Relator also facilitated American Association for Laboratory Animal Science (AALAS) certification for BCM-CCM staff and leadership, none of whom had the AALAS certifications common for their level of supervision. Relator personally held classes with all the managers to get them all AALAS certified.

34. Dr. Buckmaster received two promotions, three ascending job titles over an almost 15-year tenure with BCM, and many glowing annual performance reviews from 2011-2017.

35. Notably, Relator had an unblemished record, was never disciplined, and was never spoken to about issues with her leadership abilities or performance prior to her whistleblowing activities alleged in this FAC. It was only after Relator repeatedly brought these serious allegations and failures relating to BCM's biomedical research program to the attention of numerous BCM officials, including the IACUC, that Dr. Buckmaster was accused of "behavioral" issues

leading to her termination. Clearly, Relator's relentless efforts over a two-year period to blow the whistle on wrongdoing were the direct nexus to the termination.

Defendant

36. Defendant BCM is a private nonprofit institution, located in Houston, Texas, and the organizational applicant for the federal grants alleged in the FAC.

JURISDICTION AND VENUE

37. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a) because this is a civil action by Relator on behalf of the United States, the real party in interest, that arises under the FCA qui tam provisions, and all claims in the action form part of the same case or controversy.

38. The Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant resides, transacts business, or committed an act proscribed by the FCA, within this District.

39. Venue is proper in the Southern District of Texas, Galveston Division, under 28 U.S.C. §§ 1391(a)-(c), 1395(a), and 31 U.S.C. § 3732(a), because Defendant is located, resides, does business, or committed an act proscribed by the FCA, in this district. BCM partners with UTMB in Galveston on animal research sample and data analyses.

THE FALSE CLAIMS ACT

40. The FCA provides, in part, that any person who knowingly presents, or causes to be presented, a false claim for payment or approval; or knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for penalties and treble damages. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G). The FCA defines the term "obligation" to include an established duty arising from a grantor-grantee relationship. 31 U.S.C. § 3729(b)(3).

41. Knowingly means that the person: (1) had actual knowledge of the information; (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information. See 31 U.S.C. §§ 3729(b)(1)(A). The person need not have acted with specific intent to defraud the United States to be liable under the FCA. 31 U.S.C. §§ 3729(b)(1)(B).

42. A "claim" under the False Claims Act includes "any request or demand, whether under a contract or otherwise, for money or property . . . that is

presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A)(i).

43. The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money. 31 U.S.C. § 3729(b)(4).

44. Violations of the FCA subject the defendant to mandatory civil penalties per FCA violation, plus three times the amount of damages that the Government sustains as a result of the defendant's actions. 31 U.S.C. § 3729(a).

45. A person known as a relator may bring a civil action for a violation of 31 U.S.C. § 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. 31 U.S.C. § 3730(b)(1). If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. 31 U.S.C. § 3730(c)(3). If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been

necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant. 31 U.S.C. § 3730(d)(2).

46. An employee shall be entitled to all relief necessary to make that employee whole, if that employee is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee in furtherance of an action under this section or other efforts to stop 1 or more violations of the FCA. 31 U.S.C. § 3730(h)(1). Relief shall include reinstatement with the same seniority status that employee would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained because of the discrimination, including litigation costs and reasonable attorneys' fees. 31 U.S.C. § 3730(h)(2).

STATUTE OF LIMITATIONS

47. BCM's conduct alleged in this FAC began at least as early as 2016 and is continuing, during which time BCM received over $2 billion in taxpayer money. All the claims in this matter are timely under 31 U.S.C. §3731(b).

FEDERAL GRANTS INVOLVING BIOMEDICAL RESEARCH

48. Using animals for scientific research is highly regulated by the Federal Government because the Government is funding the research.

49. The Government has funded BCM to conduct biomedical research that BCM has promised will advance the scientific understanding and treatment of human disease and conditions such as breast and prostate cancer, heart disease, central nervous system disease, diabetes, liver and digestive diseases, neurological disorders like epilepsy, eye diseases, newborn health and development, genetic health, and allergies and asthma.

50. The Government trusts that grantees like BCM are complying with all grant requirements and acting as good stewards of taxpayer funds.

51. NIH is both a grantor and the regulator of biomedical research using animals through its Office of Laboratory Animal Welfare ("OLAW"). NIH awarded all the grants at issue to BCM and regulated BCM's compliance with its scientific animal research. 42 U.S.C. § 289d

52. There are two laws at issue (the "Animal Research Laws") that govern use of animals for biomedical research to ensure the integrity, reliability, and accountability of the studies funded by the Government.

53. First, there is the Animal Welfare Act ("AWA") and its implementing regulations. The AWA covers certain warm-blooded animals used in research. 7 U.S.C. § 2131 et seq; 9 C.F.R. § 1.1 et seq.

54. Second, the Health Research Extension Act of 1985 ("HREA") applies to all scientific research animals. 42 U.S.C. § 289d(a)(1).

55. Under the HREA, all grantees are required to properly treat and care for research animals to include the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia, and appropriate pre-surgical and post-surgical and nursing care. 42 U.S.C § 289d (2020); see also 9 C.F.R. § 2.31(e).

56. Under the HREA, NIH implemented requirements for the care and treatment of research animals. These requirements are embodied in the Public Health Service ("PHS") Policy on Humane Care and Use of Laboratory Animals ("The PHS Policy"). 42 U.S.C. § 289d(1).

57. The PHS Policy incorporates the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training" and requires the grantee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals ("The Guide"). The Guide also requires grantees to comply with numerous requirements addressing surgical procedures, the use of medication (sedation, analgesia, or anesthesia), research animals' living conditions, and the qualifications and training necessary for individuals who perform surgeries.

58. By accepting an award, under the PHS Policy, a grantee must also execute an "approved **Animal Welfare Assurance**" and "bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activity and all activity involving vertebrates, regardless of funding source." The grantee

must certify that it is complying with its Assurance in its annual report to OLAW. (emphasis added) 42 U.S.C. § 289d

59. Grantees like BCM make certifications under the Assurance, including that it:

- "will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals"
- "is guided by the 'U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training'"
- "acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance…."
- "will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use"
- "has established and will maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals" (Guide)

60. The Assurance is material to the Government's payment decision because a grantee that does not comply with its Assurance can have its grants "suspended or revoked" and its funding ceased. A grantee may be first placed on enhanced reporting to provide it notice and an opportunity to correct. 42 U.S.C. § 289d(d); 7 U.S.C. § 2143(f)

61. Further, as part of its Assurance, BCM was required to establish an Institutional Animal Care and Use Committee ("IACUC"). BCM has an IACUC, as alleged in this FAC. 42 U.S.C. § 289d; 9 CFR § 2.31.

62. BCM's IACUC was required to oversee and evaluate its biomedical research program to ensure compliance with federal requirements to include these obligations:

- Evaluate BCM's compliance with federal requirements at least once every six months and submit reports of noncompliance to the Institutional Official (the IO), the liaison between the IACUC and OLAW (the Government)
- Review and investigate potential noncompliance
- Review and approve (or withhold approval of) proposed biomedical research depending on whether the proposed research complies with federal requirements

- Ensure that individuals who perform biomedical research are qualified and properly trained
- Post-approval monitoring (PAM) to ensure the research continues to comply with federal requirements, and that any previous noncompliance has been corrected

42 U.S.C. § 289d; 9 CFR § 2.31

63. BCM's IACUC, through its IO, was also required to make certain reports to the Government as a condition of continued funding for biomedical research activities:

- **annual reports** to OLAW confirming compliance with animal welfare requirements, including compliance with its Assurance
- **promptly filed reports** to OLAW of any (a) **serious** or (b) **continuing noncompliance** with Animal Research Laws, BCM's Assurance, and IACUC-approved protocol
- **compliance progress reports** to the Grantor agency (here, NIH)

42 U.S.C. § 289d

64. The **Principal Investigator (PI)** is the lead scientist at the grantee institution who is responsible for conducting biomedical research in compliance with federal requirements, with oversight by the grantee's IACUC. 9 C.F.R. § 2.31

65. PIs and their grantee institution are accountable from the earliest stages of planning until the research is completed, including for:

- describing proposed use of animals in grant applications
- ensuring research is conducted according to **IACUC-approved protocol**
- complying with institutional policies and procedures

66. The grantee's IACUC must approve all biomedical research protocols before PIs receive federal funding to ensure they comply with federal requirements. The use of animals in the research as described in the IACUC-approved protocol must be congruent with the description in the grant application. 9 CFR § 2.31

67. Adherence to the IACUC-approved protocol is both fundamental and critical to ensure rigorous, valid, and reliable scientific data collection.

68. Before conducting biomedical research, each BCM PI Investigator must execute this certification or one materially like it:

Certification by Principal Investigator

- I certify that the use of all animals involved in this project will be carried out according to the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act Regulations, the principals of the Guide for the Care and Use of Laboratory Animals, and the policies and procedures of Baylor College of Medicine. I agree to notify the IACUC of [BCM] of any substantive changes in the research use of the animals, including the number of animals, species used, or procedures performed.
- I certify that all personnel listed on this protocol will be appropriately trained and will have completed the mandatory species-specific training (AALAS) available through BRAIN Electronic Certification and Training eCAT prior to working with any animals.
- I understand that Baylor College of Medicine and its representatives on the IACUC have the authority to suspend any part of my research, should I not be in compliance at any time with any of the above aforementioned policies, procedures, or regulations.

69. Failure to comply with any of these overlapping certifications executed by BCM, including those of its IACUC, and each of its PIs responsible for oversight of their labs, may trigger administrative sanctions and even termination of federal funding. And BCM has been put on notice of such potential consequences.

70. The Government makes clear to institutional grantees like BCM that they have ultimate responsibility over their IACUC and PIs.

> Grant recipients are collaborative partners with NIH and both parties have mutual obligations and responsibilities as stewards of Federal funds to ensure compliance with all Federal requirements. Congruence review ensures that public funds are used to promote the highest level of scientific integrity, public accountability, and social responsibility as reflected in humane animal care. Therefore, **it is the institution's responsibility, not the IACUC's, to ensure that the information the IACUC reviews and approves is consistent with that contained in the application to be funded**.

(emphasis added)

71. In summary, the regulatory framework outlined in this FAC is applicable to BCM and the allegations in the FAC.

FACTUAL ALLEGATIONS

72. To receive federal grant money, BCM certified to the Government in its Assurance that its biomedical research was compliant with IACUC-approved protocols.

73. BCM also certified that if any of its biomedical research was not conducted in accordance with IACUC-approved protocol, it would provide notice to allow the Government to evaluate the nature and severity of the noncompliance and consider the appropriateness of administrative remedies: "Any serious or continuing noncompliance with the PHS Policy and serious deviation from the provisions of the *Guide* and other relevant federal regulations are reported in writing by the IACUC, through the IO, to OLAW."

74. Despite this Assurance, however, BCM knew that its PIs systemically failed to conduct biomedical research in compliance with Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocol. Further, BCM knowingly failed to stop or discipline its PIs who were known repeat violators, or to implement measures to prevent continuing noncompliance and protect the integrity of research results.

75. Below are specific examples of serious noncompliance that BCM knowingly allowed to continue to keep the Government from turning off the funding spigot. **The examples profiled in this FAC are examples only, selected to satisfy the particularity requirements under Federal Rule of Civil Procedure 9(b); these examples are proxies for all false or fraudulent claims submitted to the Government and are not intended to represent all damages, false claims, or penalties.**

The Davis Lab

76. BCM PI Teresa Davis violated the Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocols.

77. As one example, the Davis Lab received NIH grant money for biomedical research to develop interventions to improve the growth and health of premature human infants.

78. Specifically, "young pigs" were chosen as "good animal models" for "human infants and children" to study "the effects of" different types of diets and hormones.

> Protocol AN-636: Hormone and Nutrient Effects on Protein Synthesis in Pigs
>
> The long term goal of the research is to develop nutritional and hormonal interventions to improve

> the growth of premature infants and growth-retarded infants and children. The work that is proposed is important because it will identify the mechanisms that regulate protein deposition in neonates and this will reveal new strategies to optimize the nutritional management, and hence, the outcome of low birth weight (LBW) infants.

79. "To ensure the integrity and accountability" of its research, the Davis Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, administration of medication, monitoring of research animals, compliance with euthanasia requirements, and reporting of "serious and continuing" violations, among others.

80. The Davis Lab received over $9 million in Government claims paid on all protocols through 2023.

81. Between January 2017 and June 2018, the Davis Lab committed violations on several experiments under at least this one protocol, and knowingly:

- allowed unauthorized, untrained, and unqualified individuals to conduct surgeries
- botched surgeries, killing research animals during experiments
- failed to properly euthanize research animals

- failed to properly prepare research animals for surgery
- failed to properly monitor research animals in housing area
- failed to properly maintain medical records
- failed to properly administer anesthesia
- failed to properly monitor research animals during surgery
- failed to properly close surgical wounds
- failed to follow proper sterile techniques during surgical procedures
- failed to report continuing violations to OLAW

82. BCM knew these violations were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols.

The Richards Lab

83. BCM PI Joanne Richards violated the Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocols.

84. As one example, the Richards Lab received NIH grant money for biomedical research to understand the physiology of ovarian cancer and to develop interventions to detect and prevent ovarian cancer in humans.

85. Specifically, mice were injected with hormones and studied for their response to experimental cancer suppressant medication.

> Protocol AN-721: Ovarian follicular development and hormone action
>
> Our goal is to understand the reproductive physiology of the ovary; including how hormones control follicle growth and follicle death (atresia) and how hormones stimulate ovulation to occur. In this way we hope to ensure better ways of understanding fertility and infertility. Other studies are focused on understanding the initiation and detection of ovarian cancer using specific mouse models that will lead to detection and prevention of cancer in women. Our goal is also to understand how hormones and oncogenes cause ovarian surface epithelial cancer.

86. "To ensure the integrity and accountability" of its research, the Richards Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, monitoring of research animals, administration of medication, and reporting of "serious and continuing" violations, among others.

87. The Richards Lab received over $16 million in Government claims paid on all protocols through 2023.

88. Between August 2017 and December 2019, the Richards Lab committed violations on several experiments under at least this one protocol, and knowingly:

- allowed unauthorized, untrained, and unqualified individuals to conduct surgeries
- botched surgeries, killing research animals during experiments
- failed to properly monitor research animals during surgery
- failed to follow proper sterile techniques during surgical procedures
- failed to properly close surgical wounds
- failed to properly administer pain medication for surgical procedures
- administered expired drugs to research animals in violation of DEA and OLAW requirements
- failed to report continuing violations to OLAW

89. BCM knew these violations were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols.

The Noebels Lab

90. BCM PI Jeff Noebels violated the Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocols.

91. As one example, the Noebels Lab received NIH grant money for biomedical research to identify gene mutations that lead to epilepsy in humans and to develop better treatment for epilepsy.

92. Specifically, mice were used because they are "unique models of the disorder [epilepsy]" and would "allow us to better understand this very common disorder in humans."

> Protocol AN-602: Excitability and Plasticity in Epileptic Brain
>
> We use electroencephalography (EEG) to detect abnormal brain wave patterns and seizures in mice that inherit epilepsy genes. If we are able to define the specific type of epileptic seizure that the mice show, and identify the gene responsible, we may be able to develop genetic diagnostic tests for this gene abnormality in people. By studying the brain circuitry of mice bred with this defect, we can also better understand what the defective gene has done

> to alter normal brain development. This will ultimately allow us to search for and develop much better medical therapy for this particular form of epilepsy.

93. "To ensure the integrity and accountability" of its research, the Noebels Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, monitoring of research animals, administration of medication, and reporting of "serious and continuing" violations, among others.

94. The Noebels Lab received over $23 million in Government claims paid on all protocols through 2023.

95. Between February 2016 and February 2018, the Noebels Lab committed violations on several experiments under at least this one protocol, and knowingly:

- allowed unauthorized, untrained, and unqualified individuals to conduct surgeries
- botched surgeries, improperly causing pain and requiring research animals to be euthanized
- failed to properly monitor research animals during surgery

- failed to follow proper sterile techniques during surgical procedures
- failed to properly monitor research animals postoperatively
- failed to properly administer pain medication for surgical procedures
- failed to properly administer anesthesia during surgery
- improperly performed unapproved procedures and breeding
- failed to properly monitor research animals in housing area
- failed to report continuing violations to OLAW

96. BCM knew these violations were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols.

The Rosen Lab

97. BCM PI Jeff Rosen violated the Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocols.

98. As one example, the Rosen Lab received NIH grant money for biomedical research to understand how breast cancer develops in women to promote progress in "detecting, preventing, and treating breast cancer."

99. Specifically, mice were used to "design and test new therapies that may be applicable in the treatment of human breast cancer."

Protocol AN-504: Mammary Gland Development and Breast Cancer (for example)

The goal of research in our laboratory is to understand how hormones regulate growth and differentiation in the normal mammary gland and how these regulatory mechanisms have deviated in breast cancer. Two hundred and twelve thousand nine hundred women in the U.S. will develop breast cancer this year and an estimated 40,970 women will die from breast cancer in 2006. One of eight women will develop breast cancer in her lifetime. Infiltrating ductal and invasive lobular carcinomas both appear to arise from terminal ductal epithelium of the breast and comprise 70% of all invasive breast cancer. Unfortunately, there are no good in vitro cell culture models in which to study the complex factors regulating normal mammary gland development and carcinogenesis. The elucidation of the factors regulating normal mammary development is required for an understanding of the

etiology of breast cancer. In 1998 the National Cancer Institute published a report entitled, "Charting the Course: Priorities for Breast Cancer Research." One of the principal recommendations was, "Our understanding of the biology and developmental genetics of the normal mammary gland is a barrier to progress...a more complete understanding of the normal mammary gland at each stage of development will be a critical underpinning of continued advances in detecting, preventing and treating breast cancer." In particular we are interested in understanding how hormones regulate the growth of the mammary gland following the onset of sexual maturity and during pregnancy resulting in a gland that is capable of producing large amounts of milk proteins during lactation in order to nurse newborn infants. Our studies of the regulation of milk proteins are directed at understanding how hormones regulate this normal function of the mammary gland during

> lactation, the time when the mammary cells stop growing and produce large quantities of milk.

100. "To ensure the integrity and accountability" of its research, the Rosen Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, administration of medication, and reporting of "serious and continuing" violations, among others.

101. The Rosen Lab received over $32 million in Government claims paid on all protocols through 2023.

102. Between July 2016 to August 2019, the Rosen Lab committed violations on several experiments under at least this one protocol, and knowingly:

- allowed unauthorized, untrained, and unqualified individuals to conduct surgeries
- failed to properly close surgical wounds
- failed to follow proper sterile techniques during surgical procedures
- failed to properly monitor the research animals during surgery
- failed to properly administer pain medication for surgical procedures
- failed to properly monitor research animals postoperatively
- failed to properly administer anesthesia during surgery

- violated DEA and OLAW requirements for drug use and maintenance, and administered expired drugs to research animals in violation of DEA and OLAW requirements
- failed to report continuing violations to OLAW

103. BCM knew these violations were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols.

The Zhang Lab

104. BCM PI Xiang Zhang violated the Animal Research Laws, BCM's Assurance, and the certifications made under IACUC-approved protocols.

105. As one example, the Zhang Lab received NIH grant money for biomedical research to "elucidate the biological mechanisms underlying breast cancer metastasis, which would potentially lead to novel therapies to prevent or cure metastatic disease."

106. Specifically, "human breast cancer cells will be implanted to different sites of immunodeficient mice to model metastases at various secondary organs" and "small molecular drugs will be administered to examine their effects on metastasis."

> Protocol AN-5734: The role of microenvironment in breast cancer metastasis

> The processes of tumor formation and progression require the interaction of many cell types and can only be accurately modeled with animal studies. Processes that occur along with tumor metastasis, such as migration, invasion, angiogenesis, extravasation, tumor re-initiation and colonization, are only partially modeled with in vitro systems. By using animal models, we hope to recapitulate metastatic growth of tumor cells in various distant organs. Such studies are obviously not possible in humans. Furthermore, after these metastasis models are obtained/studied, they could be used for therapeutic trials of new treatments for these diseases.

107. "To ensure the integrity and accountability" of its research, the Zhang Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, monitoring of research animals, euthanasia procedures, and reporting of "serious and continuing" violations, among others.

108. The Zhang Lab received over $10 million in Government claims paid on all protocols through 2023.

109. Between June 2016 and October 2019, the Zhang Lab committed violations on several experiments under at least this one protocol, and knowingly:

- allowed unauthorized, untrained, and unqualified individuals to conduct surgeries
- failed to follow proper sterile techniques during surgical procedures
- failed to properly administer pain medication for surgical procedures
- violated DEA and OLAW requirements for drug use and maintenance
- failed to properly administer anesthesia during surgery, and cut into an animal still responsive to pain
- failed to properly euthanize research animals
- botched surgeries
- failed to properly monitor the research animals postoperatively
- improperly allowed unapproved breeding of research animals, leading to improper overcrowding of cages
- failed to report continuing violations to OLAW

110. BCM knew these violations were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols.

111. The Davis, Richards, Noebels, Rosen, and Zhang Labs were among the repeat violators of the Animal Research Laws, BCM's Assurances, and the certifications made under IACUC-approved protocols. Further, BCM knowingly allowed the labs to commit the same violations again and again, and it knowingly failed to disclose the scope, severity, and continuing nature of the serious noncompliance to prevent the Government from turning off the funding spigot.

112. Despite its knowledge of systemic failures in its research labs, BCM knowingly and continually failed to report "serious and continuing noncompliance" to the Government dating back to at least 2016. See Exhibit A, which represents a summary chart of examples of false claims submitted to the Government and paid by the Government.

SCIENTER

113. BCM has knowingly misled the Government about the nature and extent of its "serious and continuing noncompliance" and its corrective action plans.

114. BCM is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), which is a private organization comprised of animal care experts that provides accreditation

to institutions engaged in animal research. AAALAC conducts accreditation evaluations and assigns individuals who are highly regarded experts in animal care and research, including professors, researchers, and veterinarians to conduct the evaluations.

115. Federal regulations require institutions like BCM to report to OLAW "any change…that would place the institution in a different [accreditation] category."

116. From March 13-17, 2017, AAALAC conducted a site visit at BCM and found serious violations of federal requirements, "serious items of noncompliance [that] were not consistently reported to OLAW," and failure to follow through on corrective action plans. On this basis, AAALAC "deferred accreditation"—an action whereby the institution is required to correct mandatory items and submit written response actions to address all mandatory items—only one step away from probation.

117. As one "serious item of noncompliance," AAALAC determined that BCM's IACUC had learned in June 2016 that the Rosen Lab had botched post-operative procedures but failed to report the lab's noncompliance to OLAW.

118. AAALAC also determined that BCM never disclosed to OLAW that its IACUC had uncovered at least eight incidents of "serious noncompliance" over a five-month period during 2016 and failed to report them. In at least three of

those incidents, AAALAC could find no evidence that BCM corrected the problems or sanctioned the PIs responsible for the noncompliance.

119. Only after AAALAC exposed BCM's continuing noncompliance did BCM report the noncompliance in the Rosen Lab to OLAW. However, BCM continued to withhold material information from OLAW as to the nature, extent, and timing of its continuing noncompliance and AAALAC's larger findings of noncompliance. It also falsely told OLAW that it had taken "immediate" corrective action to "halt all surgical procedures" when it had not done so; and misrepresented to OLAW that its findings resulted from a self-assessment rather than an AAALAC evaluation.

120. Based on BCM's false representations to OLAW, on April 12, 2017, OLAW responded that it "understands that measures have been implemented to improve the management and processing of reportable items. OLAW concurs with the actions taken by the institution [BCM] to comply with the PHS Policy on Humane Care and Use of Laboratory Animals."

121. As many of the examples in this FAC demonstrate, even after being placed on deferred accreditation status in 2017 for its failure to report "serious or continuing noncompliance" to OLAW, BCM continued to knowingly withhold material information from OLAW about "serious and continuing noncompliance."

122. For example, on April 25, 2018, OLAW directed BCM to require mandatory training before allowing individuals to conduct surgeries on research animals: "OLAW expects training to be conducted preemptively rather than remedially after problems occur. Please have the IACUC address this programmatic issue promptly to prevent a recurrence."

123. On July 11, 2018, OLAW placed BCM on enhanced reporting, one step removed from termination of funding. OLAW made clear to BCM that it would not "accept the piecemeal approach" to "ongoing serious programmatic noncompliance" caused by its prior failure to implement a surgical training and assessment program.

124. To prevent the stoppage of federal funds, on July 30, 2018, BCM certified to OLAW that it had begun to implement a "training ambassador" ("TA") program and would make it mandatory to ensure that no individual performed surgery until they graduated successfully from the TA program. Notably, OLAW understood from BCM that "[n]o surgery will be conducted until proficiency is verified."

125. Despite these promises and OLAW's warnings, and after being placed on enhanced reporting, BCM knowingly allowed dozens of individuals to perform hundreds of surgeries without demonstrating proficiency under the TA program. Below are some examples of surgeries performed by untrained individuals after

BCM was placed on enhanced reporting on July 11, 2018. The Government paid over $55 million in claims to these PI labs through 2023.

PRINCIPAL INVESTIGATOR (PI)	NUMBER OF SURGERIES	FALSE STATEMENTS TO OLAW?
Sanjeev Vasudevan	Over 300	YES
Eveline Barbieri	Over 200	YES
Chenghang Zong	Over 70	YES
Nabil Ahmed	Over 30	YES
Pradip Saha	Dozens	YES
Xander Wehrens	At least several	YES

126. As alleged, allowing untrained individuals to perform surgeries led to violations that were in "serious noncompliance" with Animal Research Laws, BCM's Assurance, and IACUC-approved protocols (e.g., untrained researchers botching surgeries and causing illness and death to research animals unrelated to experimental causes). This is precisely what OLAW intended to prevent by placing BCM on enhanced reporting.

127. In one example, the Wehrens Lab received NIH grant money for biomedical research to develop "a better understanding of molecular factors that trigger and maintain" atrial fibrillation (A-Fib) (an irregular and often very rapid heart rhythm (arrhythmia) [in humans] that can lead to blood clots in the heart), which "may lead to the development of more effective drugs for the treatment of [A-Fib]."

128. Specifically, mice were used for "several different cardiac studies to either induce or suppress cardiac events" through "mechanical, drug and/or gene therapy." The Wehrens Lab was then required to capture data from either living mice or after euthanasia.

> Protocol AN-4044: Phosphorylation-Dependent Regulation of Ion Channels in Atrial Fibrillation
>
> Atrial fibrillation (AF), the most common cardiac arrhythmia in humans, represents a major cause of morbidity and mortality. The incidence of AF increases with age, with a prevalence of 0.5% of people in the fifth decade rising to 10% of people in the eighth decade. In addition, patients with AF have a five-fold increased risk for stroke compared to age-matched controls, and AF is responsible for as many as 15% of all strokes. Despite the magnitude of the clinical importance and decades of research, the detailed cellular and molecular mechanisms of AF remain poorly understood. The long-term medical treatment of AF with anti-arrhythmic drug therapy is associated with a failure

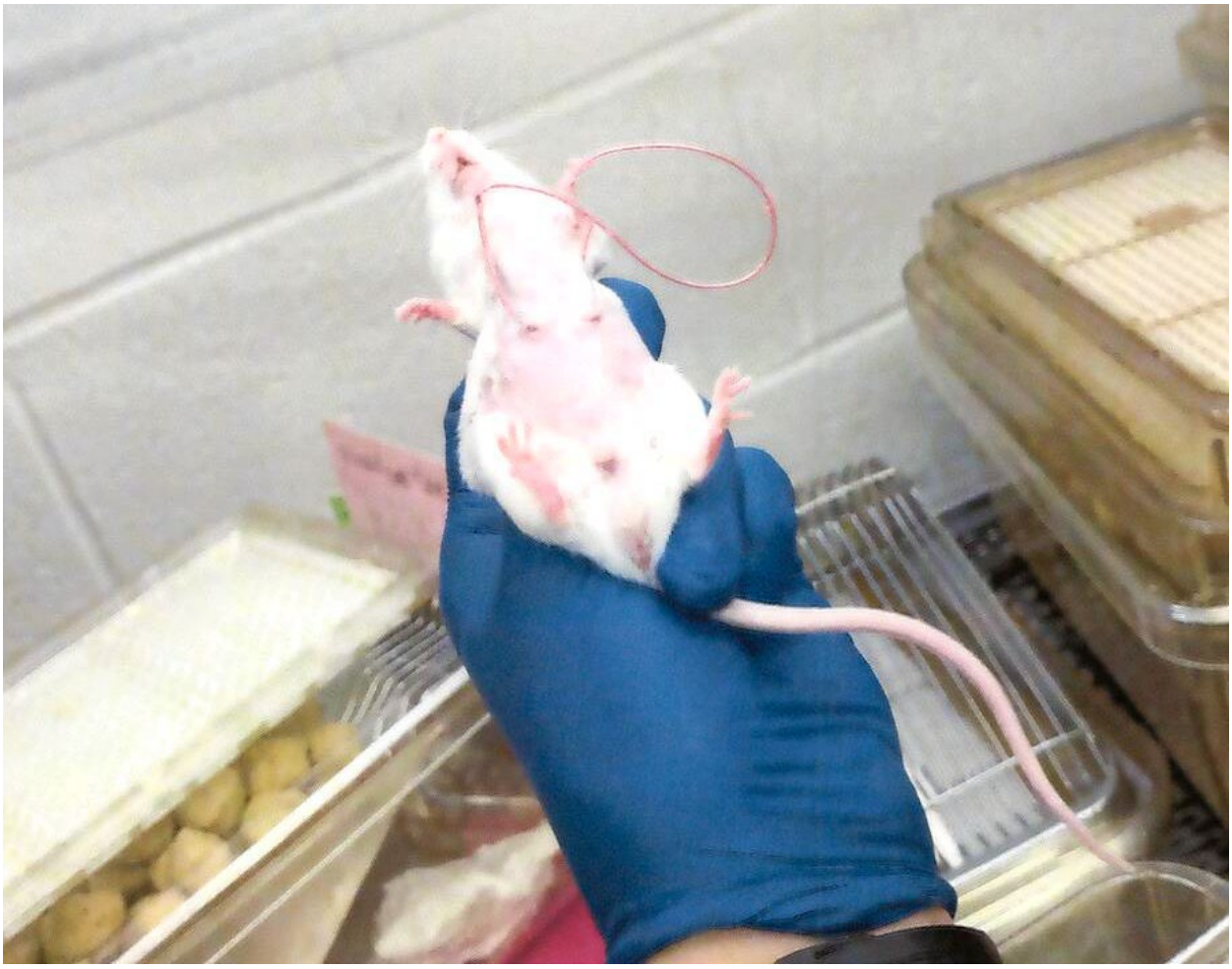
> rate of 50% at one year and up to 84% at two years. Therefore, a better understanding of molecular factors that trigger and maintain AF may lead to the development of more effective drugs for the treatment of AF. The proposed studies will use genetically altered mice to investigate the role of abnormal calcium handling in atrial fibrillation. Moreover, we intend to investigate the therapeutic potential of a novel class of drugs (calcium channel stabilizers) in mouse models of atrial fibrillation.

129. "To ensure the integrity and accountability" of its research, the Wehrens Lab was required to comply with requirements relating to proper training of individuals to perform surgical procedures, administration of medication, and monitoring of the research animals, among others.

130. The Wehrens Lab received over $15 million in Government claims paid on all protocols through 2023.

131. Yet, despite being placed on enhanced reporting and directly contrary to its promise to OLAW, BCM knowingly allowed individuals who did not graduate from the TA program to perform surgeries in the Wehrens Lab. As a result, on September 4, 2019, an untrained individual improperly laced a wire

(telemetry lead) through the skin externally on a research mouse instead of implanting it, as required by IACUC-approved protocol, as shown by this photo below.



132. This botched surgery rendered the animal useless for the study and the mouse was euthanized. This was a direct result of untrained individuals, and the death was unrelated to experimental causes. Other untrained researchers in the Wehrens Lab failed to administer pain medication as required under the IACUC-approved protocol.

133. Even worse, BCM falsely reported to OLAW that there were no problems with the research animals in this experiment, hid from OLAW the fact that more than one untrained researcher had performed surgeries after being placed on enhanced reporting, and failed to report to OLAW the death of two research animals.

134. This clear misuse of Government funds falls squarely on BCM, which is responsible for ensuring that the Government has complete and accurate information relating to noncompliance with IACUC-approved protocols. "[I]t is the institution's responsibility, not the IACUC's, to ensure that the information the IACUC reviews and approves is consistent with that contained in the application to be funded." Further, "[t]he IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to…any serious or continuing noncompliance with [the PHS] Policy…"

135. Unaware of these violations, during a site visit in September 2019, OLAW Deputy Director Axel Wolff made clear the materiality of noncompliance:

> The assurance states, signed by your institutional official, that you will report. That is the absolute expectation, and you'll report promptly and you'll fix things promptly. If investigators think, well, I

> better not report this because it could impact my grant, your grant will be much more impacted if the institution as a whole, doesn't fulfill this requirements [sic] under the assurance. . . . In Washington they always say the cover up is worse than the crime. So it's extremely important that you all continue reporting, continue monitoring your program, to protect your research funds.

136. Through its fraudulent course of conduct, BCM knowingly submitted or caused to be submitted false or fraudulent claims to the Government, in violation of the False Claims Act, and the Government paid those claims.

MATERIALITY

137. BCM's false claims and false statements were material to the Government's decision to pay claims under the federal grants.

138. BCM knew that compliance with the Animal Research Laws, their implementing regulations, the Guide for the Care and Use of Laboratory Animals, and the Public Health Service Policy, IACUC-approved protocols, and BCM's Assurance containing its certifications, were material to the Government's decision to pay BCM billions of dollars for biomedical research grants. BCM also knew that

truthful reports to the federal grantors and OLAW, its regulatory oversight body, including reports of "serious or continuing" noncompliance and corrective actions taken, were material to the Government's decision to pay BCM for biomedical research grants.

139. BCM knowingly falsely certified compliance with material requirements related to pre- and post-surgical procedures, drug administration, training of individuals prior to performing surgeries, and reporting "serious and continuing" noncompliance to the Government, and routinely failed to take steps to prevent future noncompliance.

140. BCM also knowingly submitted false reports of compliance and knowingly omitted reports of material noncompliance to the Government and used or caused to be used false statements in support of false or fraudulent claims for federal grant money in violation of the False Claims Act.

141. BCM knowingly submitted false or fraudulent annual reports, Assurances, noncompliance reports, and progress reports to the Government, and knowingly failed to report noncompliance to the Government, all of which were related to federal grant money, and all of which tainted the claims paid to BCM for biomedical research.

142. Each time that BCM applied for funding, its application included its Assurance that "[a]ny serious or continuing noncompliance with the PHS Policy . .

. and other relevant Federal regulations are reported in writing by the IACUC, through the IO, to OLAW." Thus, each time BCM applied for federal funding, having knowingly failed to report material noncompliance, as alleged in this FAC, it made a false or fraudulent claim to the Government. BCM was aware that these false or fraudulent claims were material to the Government's decision to provide or withdraw funding.

143. The allegations in this FAC demonstrate that BCM was well aware of all federal requirements and that it was unlawful to submit false or fraudulent claims or false or fraudulent statements to the Government, and further, that the violations alleged in this FAC were material to the Government's decision to pay federal grant money.

144. BCM also knew that the unlawful conduct alleged in this FAC went to the very heart of the bargain for the payment of claims for biomedical research. The Government expects and requires that federal grant money be paid only when the grantee will comply with all relevant statutes and regulations and be truthful regarding any noncompliance, including systemic noncompliance.

145. The Government's statutory and programmatic requirements for complete, accurate, and truthful reporting during Government-funded research are neither minor nor insubstantial.

146. BCM's violations were not immaterial or inadvertent technical mistakes in processing paperwork, or simple and honest misunderstandings of the rules, terms and conditions, or certification requirements. Rather, BCM failed to comply with material legal obligations and certifications undermining its research "integrity and accountability" for which the Government was paying significant money. Stated best by BCM PI Melanie Samuel after research animals died from dehydration during an experiment, this "significantly affects our breeding, our research, and our work." To cover-up its noncompliance, BCM lied to OLAW on January 13, 2020, informing it that the animals in this lab "appeared healthy with no clinical symptoms of dehydration."

147. BCM knew that false certifications of compliance with surgical and reporting requirements were material to the Government's payment decision, as shown by OLAW's placement of BCM on "enhanced reporting" in 2018 because of "serious and continuing noncompliance" with these requirements. Had OLAW been aware of continuing noncompliance during or after the period of enhanced reporting, it would have withdrawn federal funding or declined to extend new funding to BCM. When BCM knew it was facing the most severe of sanctions, the termination of its funding, it chose to misrepresent its compliance rather than become compliant.

148. In other examples, when made aware, OLAW made clear to BCM that "serious or continuing noncompliance" was material to its decision to pay claims. In 2018, OLAW reminded BCM twice that it could not use NIH grant funding for unapproved procedures including the administration of unapproved medication, and that it could not publish the data acquired from unapproved research. The overarching expectation of government funding for basic biomedical research with animals is that published data will lead to the development of medical treatments or cures for humans.

149. Under one protocol, PI Nicholas Mitsiades's lab performed procedures to generate monoclonal antibodies in 12 mice that were not approved by the IACUC. In response, on June 7, 2018, OLAW warned, "Please ensure that the NIH grant is not charged for *any* unauthorized animal activities." (emphasis added)

150. Under a different protocol, PI Xiaonan Li's lab administered an unapproved experimental drug to 19 mice. In response, on August 27, 2018, OLAW warned that "...the NIH grant is not to be charged for *any* unapproved drugs or procedures. Note also that data acquired during the conduct of activities not approved by the [IACUC] usually cannot be published." (emphasis added)

151. BCM was repeatedly put on notice of what the Government considered material to its decision to pay claims under biomedical research grants.

152. The False Claims Act is the appropriate remedy for grant fraud cases involving biomedical research as shown by the declined False Claims Act qui tam case resolved by a whistleblower with the approval of the Department of Justice. In 2019, Duke University paid over $100 million to resolve allegations that it submitted false claims under federal grants for biomedical research, causing the Government to pay claims to Duke that it otherwise would not have paid. https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related

153. In January 2023, Hunter College and one of its professors paid a False Claims Act settlement and admitted wrongdoing for allegedly misusing NIH grant funds. The United States Attorney for the Southern District of New York observed that "NIH provides funding to academic institutions for the purpose of furthering important research that impacts communities and improves lives….When individuals and institutions abuse federal grant money, this Office will hold them accountable." https://www.justice.gov/usao-sdny/pr/us-attorney-announces-settlement-civil-fraud-lawsuit-against-former-hunter-college; https://www.justice.gov/usao-sdny/press-release/file/1564846/download

154. In another False Claims Act qui tam case in 2013, a judgment was entered against a meat packing company for over $155 million for allegations of inhumane handling of cattle, circumventing cattle inspections, and false

representations regarding the company's eligibility to process beef, which potentially impacted ground beef provided to children in a federally assisted meal program called the National School Lunch Program. Just like the children put at risk, BCM's false statements of compliance with federal grant requirements put at risk the "integrity and accountability" of its biomedical research. https://www.justice.gov/opa/pr/us-intervenes-suit-against-former-beef-suppliers-national-school-lunch-program; https://www.justice.gov/usao-cdca/pr/former-supplier-beef-national-school-lunch-program-settle-allegations-improper

155. In a non-False Claims Act case in the U.S. District Court for the Western District of Virginia, the Department of Justice entered a consent decree with a private company that breeds and sells animals for research, to permanently prohibit the company from engaging in any such activity and to remove all beagles from its facility because of violations of the same Animal Welfare Act at issue in this case. The AWA violations included the handling, housing, feeding, watering, sanitation, and adequate veterinary care of the dogs. The DOJ official stated, "We will continue to vigorously enforce animal welfare laws to ensure that animals are provided the humane care that they are legally owed and deserve." This case is important here because it also demonstrates the materiality of violations of the AWA to the Government. https://www.justice.gov/opa/pr/justice-department-secures-surrender-over-4000-beagles-virginia-breeder-dogs-research.

156. In short, there is ample evidence to show that BCM knew or should have known that its violations had the natural tendency to influence the Government's decision to pay claims for biomedical research and that any reasonable person would attach importance to BCM's choice of action.

RETALIATION

157. At least as early as 2016, Relator repeatedly and consistently informed BCM officials including IACUC members, the Chair of the IACUC, and the Institutional Official of concerns related directly to the allegations set forth in this FAC because Relator was troubled that BCM was engaged in the unlawful systemic practices alleged in this FAC.

158. Yet, Relator was ignored, placated, reprimanded, retaliated against, and terminated by BCM officials when raising concerns related to, and objecting to, the pattern and practice alleged in this FAC.

159. BCM terminated Relator on October 2, 2019, because of lawful acts by Relator to stop one or more violations of the False Claim Act and lawful acts by Relator in furtherance of an action under 31 U.S.C. § 3730.

160. Below are some specific events that occurred, which are relevant to the retaliation allegations in this FAC.

161. After serving for six years as BCM-CCM's Associate Director of Training and then its Associate Director of Training and Operations, Relator

became its director and was employed by BCM for nearly 15 years. After becoming Director, Relator voiced her concerns that BCM was allowing unauthorized, untrained, and unqualified individuals to perform surgeries. Over time, her voice became louder.

162. In one example, on April 25, 2018, OLAW took notice and sent BCM a letter reminding it to properly train individuals before allowing them to engage in surgical procedures with research animals. This letter coincided with Relator's growing concerns about issues with staff training, and the fact that BCM was falsely reporting to OLAW that it was complying with training requirements. However, the IACUC took no immediate action in response to the letter. Despite Relator's development of a robust surgical training program in 2016, BCM leadership refused to make it mandatory.

163. On May 12, 2018, Relator, along with 10 other BCM-CCM employees including the Attending Veterinarian (Rebecca Schwiebert) penned a letter to the IACUC addressing their collective ongoing concerns about BCM's failure to ensure individuals were trained before allowing them to perform surgeries. Relator continued to press the issue at a meeting with the IACUC in or around June 2018. However, the IACUC voted against implementing such protocols. Relator and Attending Veterinarian Schwiebert sent the then-IO (Adam

Kuspa) several additional correspondences after the June 2018 IACUC meeting asking that Kuspa and the IACUC reconsider their position.

164. Over the next 16 months, Relator began to suffer ongoing harassment and retaliation. Relator regularly heard from other employees that the individual who was next in line to become Relator's boss (Dean of Research/IO Mary Dickinson) wanted to find a way to push Relator out. Relator was told that an "anonymous complaint" was filed against her for "behavior" during the previously mentioned IACUC meeting, which Human Resources decided not to investigate, but about which Relator was still reprimanded. Relator was told that another "anonymous complaint" was filed against her in May 2019, which was investigated by Employee Relations and not substantiated. Finally, Relator was ultimately terminated on October 2, 2019, in direct nexus to lawful acts by her in furtherance of actions to stop violations of 31 U.S.C. § 3730.

165. Shortly before Relator was terminated, on September 19, 2019, OLAW conducted an on-site visit at BCM at which Relator was present. On the visit, OLAW expressed concerns about whether the IACUC was complying with federal requirements relating to surgical procedures. By email, Relator shared her similar concerns with OLAW on September 29, 2019. On September 30, 2019, Dean Dickinson contacted Relator around 4:15 pm asking her to meet at 4:30 pm. Relator had left for the day already, so she was unable to meet with the Dean, and

was out sick on October 1, 2019. Also, on October 1, Relator notified Dean Dickinson by email: "I want you to be advised that I have protested programmatic noncompliance by Baylor College of Medicine's (BCM) researchers, Institutional Animal Care and Use Committee (IACUC) and IACUC Office to the Office of Laboratory Animal Welfare (OLAW) – National Institutes of Health (NIH). I will consider any adverse action taken against me to be in retaliation for my having expressed my concerns and appropriately reported these concerns to OLAW – NIH."

166. On the morning of October 2, 2019, Relator was called into a meeting with Dean Dickinson and an individual from Employee Relations (Leigh Knubley). Relator was immediately informed that her employment as Director of BCM-CCM was terminated. The prompted explanations given to Relator for her termination were: 1) the College was attempting to "reorganize," 2) the College would like to go in a "different direction," and 3) Relator was "not fulfilling her leadership role" within the College. After some probing from Relator, BCM officials stated, "We need to establish the strongest possible program, and you have built a lot of the tenets of that, but we need to move forward from this position and really look at the business operations..." That is the totality of explanation Relator was given for this unceremonious termination. Finally, as Relator was leaving the room, BCM officials added, "Just to be clear - you're going to leave today, you're not going to

contact your staff, right? And you're not going to engage in disparaging activities?"

167. On October 2, 2019, not three weeks into the Dean Dickinson's tenure, Relator's employment was terminated without cause. Notably, Dean Dickinson had been in several meetings at which Relator voiced her ongoing concerns. There was an additional meeting at which the Dean took issue with Relator's "behavior." Relator also learned of several conversations the new Dean was having with Relator's subordinates about removing her in or around September 2019, which Dean Dickinson later confirmed when confronted by Relator.

168. Also notably, Relator had never received any type of performance improvement plan, or any otherwise negative performance evaluations. BCM was clearly attempting to handle Relator's termination in a secretive manner, outside normal policy and procedure for handling disciplinary matters as per the BCM Progressive Discipline Policy, which states that "supervisors or issuing authorities will issue formal progressive discipline warnings to address deficiencies in performance, conduct, or policy violations via the steps outlined below." Steps include: 1. Verbal Counsel; 2. 1st Warning; 3. 2nd Warning; 4. 3rd Warning or Termination. Relator received no formal warnings or counsel prior to her

termination, demonstrating that in this instance BCM acted outside the bounds of normal policy and procedure.

169. As stated, Relator had an unblemished record for 13 years. It was only after Relator repeatedly brought "serious and continuing noncompliance" to the attention of numerous BCM officials, as alleged in this FAC, that she was accused of "behavioral" issues leading to her termination. Clearly, Relator's relentless efforts to blow the whistle on wrongdoing were the direct nexus to the termination.

170. For the reasons set forth in this FAC, Relator is entitled to double the amount of back pay, interest on the back pay and compensation for any special damages sustained because of the discrimination, including litigation costs and reasonable attorneys' fees, and all other remedies and recompense allowable under 31 U.S.C. § 3730(h).

COUNT I
Federal False Claims Act:
31 U.S.C. § 3729(a)(1)(A)

171. The allegations in the preceding paragraphs are incorporated by reference.

172. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

173. The United States paid for claims that otherwise would not have been allowed.

174. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act, and liable for all other relief authorized by statute.

175. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

COUNT II
Federal False Claims Act:
31 U.S.C. § 3729(a)(1)(B)

176. The allegations in the preceding paragraphs are incorporated by reference.

177. Defendant knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729 (a)(1)(B).

178. The United States paid for claims that otherwise would not have been allowed.

179. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus

civil penalties for each violation of the Act, and liable for all other relief authorized by the statute.

180. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

COUNT III
Federal False Claims Act:
31 U.S.C. § 3729(a)(1)(G)

181. The allegations in the preceding paragraphs are incorporated by reference.

182. Defendant knowingly made, used, or caused to be made or used false records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729 (a)(1)(G).

183. The United States paid for claims that otherwise would not have been allowed.

184. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act, and liable for all other relief authorized by the statute.

185. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

COUNT IV
Retaliation of Relator in Violation of False Claims Act
31 U.S.C. § 3730(h)

186. The allegations in the preceding paragraphs are incorporated by reference.

187. Relator engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3730.

188. Because of Relator's lawful acts, Relator was subject to retaliation by Defendant.

189. Relator was unlawfully retaliated against by Defendant and for engaging in protected activity, namely for raising, objecting to, and refusing to participate in fraudulent conduct alleged in this FAC.

190. Defendant's retaliation against Relator was a violation of 31 U.S.C. § 3730(h).

191. Because of Defendant's violations of 31 U.S.C. § 3730(h), Relator suffered damages.

192. Relator is entitled to damages sustained as a result of the retaliation, including litigation costs and reasonable attorneys' fees, and all other remedies and recompense allowable under 31 U.S.C. § 3730(h).

193. As a direct and proximate result of Defendant's retaliatory actions, Relator suffered damages and is entitled to all allowable relief under the federal False Claims Act, 31 U.S.C. § 3730(h).

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of Relator and the United States, prays:

(a) That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of any amount within the applicable statutory ranges, for each violation;

(b) That Relator be awarded an amount that the Court decides is reasonable for recovering the proceeds of the action, including but not limited to the civil penalties and damages, on behalf of the United States, which, pursuant to the False Claims Act, shall be not less than 25 percent nor more than 30 percent of the proceeds of the action or settlement of the claim;

(c) That Relator receive all relief necessary to make Relator whole for Defendant's violations of 31 U.S.C. § 3730(h);

(d) That the Court order Defendant to award Relator front pay in lieu of reinstatement;

(e) That Relator receive an award of two times back pay, including the value of lost benefits and equity;

(f) That Relator receive an award of compensatory damages in an amount to be proven at trial for the economic, reputational, and emotional harm Relator experienced as a result of Defendant's unlawful conduct;

(g) That Relator be awarded all costs and expenses incurred, including reasonable attorneys' fees; and

(h) That the Court order such other relief as is appropriate.

Trial by jury is hereby requested.

Dated: April 3, 2023.

Respectfully submitted,

/s/ Andrea L. Meza

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/s/ John R. Thomas, Jr.

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Certificate of Service

I, Andrea L. Meza, do hereby certify that on April 3, 2023, a copy of the forgoing First Amended Complaint was filed via Electronic Case Files. Notice of this filing will be sent to the following parties through the Electronic Case Filing System. Parties may access this filing through the Court's System.

Sara Brinkmann
Partner
King & Spalding
1100 Louisiana
Suite 4100
Houston, TX 77002
sbrinkmann@kslaw.com
713-751-3279
Counsel for Baylor College of Medicine

I further certify that on April 3, 2023, Defendant, through counsel, has agreed to waive service of the summons and complaint, and accept a copy of the foregoing First Amended Complaint and Galveston Division Rules of Practice, which was served via electronic mail and properly addressed to the following:

Sara Brinkmann
Partner
King & Spalding
1100 Louisiana
Suite 4100
Houston, TX 77002
sbrinkmann@kslaw.com
713-751-3279

EXHIBIT A

PRINCIPAL INVESTIGATOR (PI)	PROTOCOL PROFILED IN THE FIRST AMENDED COMPLAINT	BIOMEDICAL RESEARCH AREA	NONCOMPLIANCE	MET GOVERNMENT REQUIREMENTS FOR SCIENTIFIC RIGOR?	MOST RECENT KNOWN NONCOMPLIANCE ON ANY GOVERNMENT PROTOCOL	GOVERNMENT CLAIMS PAID ON ALL PROTOCOLS THROUGH 2023
Teresa Davis	AN-636: Hormone and Nutrient Effects on Protein Synthesis in Pigs	Premature infant growth and health	•allowed unauthorized, untrained, and unqualified individuals to conduct surgeries •botched surgeries, killing research animals during experiments •failed to properly euthanize research animals •failed to properly prepare research animals for surgery •failed to properly monitor research animals in housing area •failed to properly maintain medical records •failed to properly administer anesthesia •failed to properly monitor research animals during surgery •failed to properly close surgical wounds •failed to follow proper sterile techniques during surgical procedures •failed to report continuing violations to OLAW	**NO**	At least June 2018	Over $9 million
Joanne Richards	AN-721: Ovarian follicular development and hormone action	Ovarian cancer, fertility & infertility	•allowed unauthorized, untrained, and unqualified individuals to conduct surgeries •botched surgeries, killing research animals during experiments •failed to properly monitor research animals during surgery •failed to follow proper sterile techniques during surgical procedures •failed to properly close surgical wounds •failed to properly administer pain medication for surgical procedures •administered expired drugs to research animals in violation of DEA and OLAW requirements •failed to report continuing violations to OLAW	**NO**	At least December 2019	Over $16 million
Jeff Noebels	AN-602: Excitability and Plasticity in Epileptic Brain	Epilepsy	•allowed unauthorized, untrained, and unqualified individuals to conduct surgeries •botched surgeries, improperly causing pain and requiring research animals to be euthanized •failed to properly monitor research animals during surgery •failed to follow proper sterile techniques during surgical procedures •failed to properly monitor research animals postoperatively •failed to properly administer pain medication for surgical procedures •failed to properly administer anesthesia during surgery •performed unapproved procedures and breeding •failed to properly monitor research animals in housing area •failed to report continuing violations to OLAW	**NO**	At least February 2018	Over $23 million
Jeff Rosen	AN-504: Mammary Gland Development and Breast Cancer	Breast cancer	•allowed unauthorized, untrained, and unqualified individuals to conduct surgeries •failed to properly close surgical wounds •failed to follow proper sterile techniques during surgical procedures •failed to properly monitor the research animals during surgery •failed to properly administer pain medication for surgical procedures •failed to properly monitor research animals postoperatively •failed to properly administer anesthesia during surgery •violated DEA and OLAW requirements for drug use and maintenance, and administered expired drugs to research animals in violation of DEA and OLAW requirements •failed to report continuing violations to OLAW	**NO**	At least August 2019	Over $32 million
Xiang Zhang	AN-5734: The role of the microenvironment in breast cancer metastasis	Breast cancer metastasis	•allowed unauthorized, untrained, and unqualified individuals to conduct surgeries •failed to follow proper sterile techniques during surgical procedures •failed to properly administer pain medication for surgical procedures •violated DEA and OLAW requirements for drug use and maintenance •failed to properly administer anesthesia during surgery, and cut into an animal still responsive to pain •failed to properly euthanize research animals •botched surgeries •failed to properly monitor the research animals postoperatively •improperly allowed unapproved breeding of research animals, leading to improper overcrowding of cages •failed to report continuing violations to OLAW	**NO**	At least October 2019	Over $10 million